



Scientific Opinion on the substantiation of a health claim related to glycaemic carbohydrates and contribution to normal cognitive function pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to glycaemic carbohydrates and contribution to normal cognitive function pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Dextro Energy GmbH & Co. KG, submitted for the authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to glycaemic carbohydrates and contribution to normal cognitive function. The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The Panel considers that the food constituent, glycaemic carbohydrates, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect. Contribution to normal cognitive function is a beneficial physiological effect. Glycaemic carbohydrates contribute to the maintenance of normal brain functions, including cognition. The Panel concludes that a cause and effect relationship has been established between the consumption of glycaemic carbohydrates and contribution to normal cognitive function. A daily intake of 130 g of glycaemic carbohydrates has been estimated to cover the glucose requirement of the brain. Such amounts can be consumed as part of a balanced diet. The target population is the general population.

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KEY WORDS

glycaemic carbohydrates, cognitive function, health claims

¹ On request from the Competent Authority of Germany following an application by Dextro Energy GmbH & Co. KG, Question No EFSA-Q-2014-00555, adopted on 6 February 2015.

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SUMMARY

Following an application from Dextro Energy GmbH & Co. KG, submitted for the authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to glycaemic carbohydrates and contribution to normal cognitive function.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

The applicant proposed “glucose” as the food constituent that is the subject of the health claim. From the information provided by the applicant, the Panel considers that the food constituent that is the subject of the health claim is glycaemic carbohydrates, which are dietary sources of glucose. The Panel considers that glycaemic carbohydrates are sufficiently characterised in relation to the claimed effect.

The claimed effect proposed by the applicant is “contributes to normal cognitive function”. The target population proposed by the applicant is the general population. The Panel considers that contribution to normal cognitive function is a beneficial physiological effect.

Glycaemic carbohydrates contribute to the maintenance of normal brain functions, including cognition.

The Panel concludes that a cause and effect relationship has been established between the consumption of glycaemic carbohydrates and contribution to normal cognitive function.

A daily intake of 130 g of glycaemic carbohydrates has been estimated to cover the glucose requirement of the brain. Such amounts can be consumed as part of a balanced diet. The target population is the general population.

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BACKGROUND

Regulation (EC) No 1924/2006⁴ harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 01/08/2014.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- On 10/09/2014, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 10/11/2014, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 27/11/2014.
- During its meeting on 06/02/2015, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to glycaemic carbohydrates and contribution to normal cognitive function.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: glycaemic carbohydrates and contribution to normal cognitive function.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of glycaemic carbohydrates, a positive assessment of its safety, nor a decision on whether glycaemic carbohydrates are, or are not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Dextro Energy GmbH & Co. KG, Hafenstrasse 77, 47809, Krefeld, Germany.

Food/constituent as stated by the applicant

According to the applicant, the food constituent that is the subject of the health claim is glucose (synonymous dextrose), $C_6H_{12}O_6$, $M=180.16$ g/mol.

Health relationship as claimed by the applicant

According to the applicant, the claimed effect is normal cognitive function. For the human body, energy is available in the form of the cellular energy-carrying molecule such as adenosine triphosphate, most of which is generated through aerobic cellular respiration of carbohydrate such as glucose. Thus, glucose is the preferred energy source for most body cells including the brain which requires glucose for its energy needs, it consumes 20 % of the energy provided by the diet. Glucose is ingested in form of monosaccharides or in form of di- oligo- and polysaccharides, mainly starch, which has to be broken down into its constituent monosaccharide glucose before absorption.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "glucose contributes to normal cognitive function".

Specific conditions of use as proposed by the applicant

According to the applicant, the target population is the general population.

According to the applicant, a total intake of 130 g of dietary glycaemic carbohydrates (e.g. glucose) per day, for both children (>1 year) and adults, is estimated to cover the whole glucose requirement of the brain and its general function. According to the applicant, lower amounts of glucose which do not cover the total glucose requirements of the brain nevertheless contribute to its normal function and to unique cognitive processes. Ingestion of a significant amount of carbohydrates might be defined as 15 % (about 20 g) of the daily dose of 130 g carbohydrates needed for normal brain function. Analogous to the condition of use for vitamins and minerals 15 % should also be seen as significant and defined as the condition of use of the claim for glucose and normal cognitive function.

ASSESSMENT**1. Characterisation of the food/constituent**

The applicant proposed "glucose" as the food constituent that is the subject of the health claim.

Glucose is one of the main glycaemic carbohydrates in the diet. Glycaemic carbohydrates can be classified, according to their degree of polymerisation, as simple (monosaccharides and disaccharides) or complex (oligosaccharides and polysaccharides). Glycaemic carbohydrates are digested and absorbed in the human small intestine, and provide glucose to body cells as a source of energy (EFSA NDA Panel, 2010).

From the information provided by the applicant, the Panel considers that the food constituent that is the subject of the health claim is glycaemic carbohydrates, which are dietary sources of glucose.

The Panel considers that the food constituent, glycaemic carbohydrates, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is “contributes to normal cognitive function”. The target population proposed by the applicant is the general population.

Cognitive function encompasses several domains, including memory, attention, alertness, learning, intelligence, language and problem solving, which are well-defined psychological constructs.

The Panel considers that contribution to normal cognitive function is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

Glycaemic carbohydrates are the main source of energy in most human diets. Glucose is the preferred energy source for most body cells. The brain requires glucose for its energy needs. An intake of 130 g of dietary glycaemic carbohydrates per day, for both children (>1 year) and adults, is estimated to cover the glucose requirement of the brain (IoM, 2005; EFSA NDA Panel, 2010).

Glycaemic carbohydrates contribute to the maintenance of normal brain functions (EFSA NDA Panel, 2011), including cognition.

The Panel concludes that a cause and effect relationship has been established between the consumption of glycaemic carbohydrates and contribution to normal cognitive function.

The Panel considers that the conditions of use for the claim on glycaemic carbohydrates and maintenance of normal brain function, which was assessed by the Panel with a favourable outcome, also apply to this claim on glycaemic carbohydrates and contribution to normal cognitive function (EFSA NDA Panel, 2011).

4. Panel’s comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: “glycaemic carbohydrates contribute to normal cognitive function”.

5. Conditions and restrictions of use

A daily intake of 130 g of glycaemic carbohydrates has been estimated to cover the glucose requirement of the brain. Such amounts can be consumed as part of a balanced diet. The target population is the general population.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, glycaemic carbohydrates, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.
- The claimed effect proposed by the applicant is “contributes to normal cognitive function”. The target population proposed by the applicant is the general population. Contribution to normal cognitive function is a beneficial physiological effect.

- A cause and effect relationship has been established between the consumption of glycaemic carbohydrates and contribution to normal cognitive function.
- The following wording reflects the scientific evidence: “glycaemic carbohydrates contribute to normal cognitive function”.
- A daily intake of 130 g of glycaemic carbohydrates has been estimated to cover the glucose requirement of the brain. Such amounts can be consumed as part of a balanced diet. The target population is the general population.

DOCUMENTATION PROVIDED TO EFSA

1. Health claim application on glycaemic carbohydrates and contribution to normal cognitive function pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No 0421_DE). August 2014. Submitted by Dextro Energy GmbH & Co. KG.

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- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition, and Allergies), 2010. Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. EFSA Journal 2010;8(3):1462, 77 pp. doi:10.2903/j.efsa.2010.1462
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- IoM (Institute of Medicine), 2005. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. The National Academies Press, Washington DC, USA.